



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,068	10/06/2003	Oleg Svanidze	816020-100052-US	9947
34026	7590	05/02/2005	EXAMINER	
JONES DAY			MILLER, CHERYL L	
555 WEST FIFTH STREET, SUITE 4600			ART UNIT	
LOS ANGELES, CA 90013-1025			PAPER NUMBER	
			3738	
DATE MAILED: 05/02/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

58

Office Action Summary	Application No.	Applicant(s)	
	10/680,068	SVANIDZE ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-16, 18-32, 34-38, 41-45 is/are rejected.
- 7) ☒ Claim(s) 8, 17, 33, 39 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of species 16, drawn towards figures 40-44 is acknowledged by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7, 9, 15, 29, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the support structure" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 6 and 29 both recite, "multiple reservoirs". It is unclear whether these multiple reservoirs are in addition to the reservoir claimed in 1 (or 23), or if the reservoir in claim 1 (23) comprises multiple reservoirs. Claim 7 depends on claim 6 and inherits all problems with the claim (it is unclear which "reservoir" the applicant is referring to). Similar errors occur with claim 9, 31, and 32. It is unclear what "separate reservoirs" is referring to, since only one reservoir has been claimed.

It is also noted to the applicant that claims 10-13, 17, and 18 contain product-by-process limitations. Since there are dependent upon a product claim, the process limitations are not necessarily given patentable weight. See MPEP 2113.

\Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Somyk (US 3,571,815). Somyk disclose an assembly (25) comprising an anchoring structure (31+26), a collapsible valve (32) connected to the anchoring structure, an outer circumferential reservoir (30; see fig.5) positioned at an outermost radius of the anchoring structure (edge of 26), and a sealable fixation compound (35) housed within the reservoir (fig.5). Somyk discloses the valve (32) to be positioned internal of the anchor structure (31+26) and wherein the valve (32) is non-biological.

Claims 1-5, 10-15, and 18-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Obermiller (US 2004/0210301 A1). Obermiller discloses an assembly (fig.46) comprising an anchoring structure (frame 11), collapsible valve (covering 45) connected to the anchoring structure (11), an outer circumferential reservoir (channel formed from rolled portion in fig.46; reservoir extends around the outside of frame 11) positioned at an outermost radius of the anchor structure, and a sealable fixation (144) compound housed in the reservoir. Obermiller discloses a

Art Unit: 3738

self-expanding or balloon expanding anchoring structure (11) and a biological or non-biological valve (45, [0067]) having 2 or 3 leaflets (fig. 45, 35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11-16, 18-30, 34-38, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,458,153 B1) in view of Sherry (US 2003/0074058 A1). Bailey discloses an assembly and method of implanting the assembly comprising providing an anchoring structure (self-expanding or balloon expandable stent-graft; 12+11; fig. 1) and a collapsible valve (26) connected to the anchoring structure (11+12). Bailey does not disclose however, a reservoir having a sealable fixation compound attached to the anchoring structure. Sherry teaches in the same field of vascular devices, an anchoring structure (stent-graft 12) having an outer circumferential reservoir (16, 34) housing the claimed sealable fixation compounds (18; [0013, 0037, 0043], in order to improve the seal between the anchor structure and the vessel wall [0041, 0036]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Bailey's anchoring structure with Sherry's teaching of attaching sealant housed reservoirs with anchoring structures, in order to improve the seal between anchor structures and vessel walls.

Art Unit: 3738

Claims 1-6, 11, 13-15, 18-29, 34, 36-38, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,458,153 B1) in view of Fogarty et al. (US 6,656,214 B1). Bailey discloses an assembly and method of implanting the assembly comprising providing an anchoring structure (self-expanding or balloon expandable stent-graft; 11+12; fig.1) and a collapsible valve (26) connected to the anchoring structure (11+12). Bailey does not disclose however, a reservoir having a sealable fixation compound attached to the anchoring structure. Fogarty teaches in the same field of vascular devices, an anchoring structure (stent-graft; col.5, lines 25-28; 200) having an outer circumferential reservoir (cuff permeable membrane, col.7, lines 35-40) housing the claimed sealable fixation compound (hydrogel; col.7, lines 40-45), in order to improve the seal between the anchor structure and the vessel wall (col.7, lines 35-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Bailey's anchoring structure with Fogarty's teaching of attaching sealant housed reservoirs with anchoring structures, in order to improve the seal between anchor structures and vessel walls.

Allowable Subject Matter

Claims 8, 17, 33, 39, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7, 9, 31, and 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER